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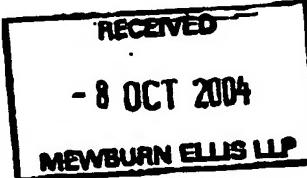
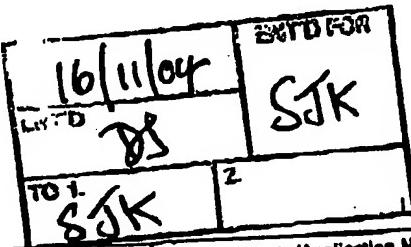
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**SJK/FP5842554**

Anmeldung Nr./Application No./Demande n° // Patent Nr./Patent No./Brevet n°  
**99933581.3-1222/US9914486**

Anmelder/Applicant/Demandeur/Patentinhaber/Propriétaire/Titulaire  
**Virologic, Inc.**

## COMMUNICATION

The European Patent Office herewith transmits the partial European search report under Rule 46(1) EPC relating to the above-mentioned European patent application.

Copies of the documents cited in the search report are enclosed.

The applicant's attention is drawn to the following:

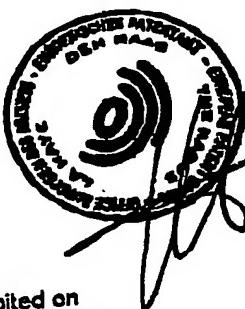
The search Division informs the applicant that if the European search report is also to cover inventions other than the invention first mentioned in the claims, a further search fee must be paid for each of these inventions, within ONE MONTH after notification of this communication.

If the application has been filed up to 30 June 1999, the search fee in force before 01 July 1999 (EUR 869.-) or the equivalent applicable on the date of payment is payable.

This applies also to the search fees requested under Rule 46(1) EPC.  
See also OJ EPO 08/1999, 405.

The abstract was modified by the Search Division and the definitive text is attached to the present communication.

Additional set(s) of copies of the documents cited in the European search report is (are) enclosed as well.



### Note to users of the automatic debiting procedure:

Unless the EPO receives prior instructions to the contrary, the search fee(s) will be debited on the last day of the period for payment. For further details see the Arrangements for the automatic debiting procedure, Supplement to OJ EPO 02/1999.

REGISTERED LETTER

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**SUPPLEMENTARY  
PARTIAL EUROPEAN SEARCH REPORT**  
under Rule 46, paragraph 1 of the European Patent Convention

Application Number

EP 99 93 3581

DOCUMENTS CONSIDERED TO BE RELEVANT		Relevant to claim	CLASSIFICATION OF THE APPLICATION (INCLAS)
Category	Citation of document with indication, where appropriate, of relevant passages		
X	WO 97/27332 A (INNOGENETICS NV ; STUYVER LIEVEN (BE); LOUWAGIE JOOST (BE); ROSSAU RUD) 31 July 1997 (1997-07-31) * page 4, line 15 - page 5, line 11 *	1-7	C12Q1/68 C12Q1/70 C12N13/00 C07H21/02 C07H21/04 A01N43/04
Y	* page 6, line 15 - page 7, line 15 * + page 13, line 26 - line 29 * * page 22, line 19 - line 21 * + tables 1-3 *	17, 18, 20-31	
D, Y	WO 97/27319 A (VIROLOGIC INC) 31 July 1997 (1997-07-31) * claims 1,5,12,28,32,33,88,90,93 *	17, 18 -/-	

TECHNICAL FIELDS  
SEARCHED (INCLAS)

C12Q

**LACK OF UNITY OF INVENTION**

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

The present partial European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims.		
3	Place of search	Date of completion of the search
	The Hague	24 September 2004
	Examiner	
	Schmitt. A	
CATEGORY OF CITED DOCUMENTS		
X: particularly relevant if taken alone Y: particularly relevant if combined with another document of the same category A: technological background O: non-written disclosure P: intermediate document		
T: theory or principle underlying the invention E: earlier patent document, but published on, or after the filing date D: document cited in the application L: document cited for other reasons & member of the same patent family, corresponding document		



European Patent  
Office

PARTIAL EUROPEAN SEARCH REPORT

Application Number  
EP 99 93 3581

DOCUMENTS CONSIDERED TO BE RELEVANT		CLASSIFICATION OF THE APPLICATION (InCLC)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim
Y	IVERSEN A K N ET AL: "MULTIDRUG-RESISTANT HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 STRAINS RESULTING FROM COMBINATION ANTIRETROVIRAL THERAPY" JOURNAL OF VIROLOGY, THE AMERICAN SOCIETY FOR MICROBIOLOGY, US, vol. 70, no. 2, 1 February 1996 (1996-02-01), pages 1086-1090, XP002031823 ISSN: 0022-538X * the whole document *	17, 18, 22-25, 28-31
A		1-7, 20, 21, 26, 27
Y	FITZGIBON J E ET AL: "HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 POL GENE MUTATIONS IN AN AIDS PATIENT TREATED WITH MULTIPLE ANTIRETROVIRAL DRUGS" JOURNAL OF VIROLOGY, THE AMERICAN SOCIETY FOR MICROBIOLOGY, US, vol. 67, no. 12, December 1995 (1995-12), pages 7271-7275, XP002934804 ISSN: 0022-538X * the whole document *	20, 21, 24-27
Y	CLERCQ DE E: "DEVELOPMENT OF RESISTANCE OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) TO ANTI-HIV AGENTS: HOW TO PREVENT THE PROBLEM?" INTERNATIONAL JOURNAL OF ANTIMICROBIAL AGENTS, AMSTERDAM, NL, vol. 9, no. 1, 1997, pages 21-36, XP000878561 ISSN: 0924-8579 * the whole document *	17, 18
A		1-7, 20-31
3		-/-



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# PARTIAL EUROPEAN SEARCH REPORT

Application Number

EP 99 93 3581

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (IPC6)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	TECHNICAL FIELDS SEARCHED (IPC6)
A	KANKI P J ET AL: "VIROLOGY OF HIV-1 AND HIV-2: IMPLICATIONS FOR AFRICA" AIDS, LONDON, GB, vol. 11, no. SUPPL B, 1997, pages S33-S42, XP008035289 ISSN: 0269-9370 + the whole document *		
3	EPO FORM 1990 (EPO C 10)		



The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. claims: 1-7, 17, 18, 20-31 (completely)

Method for assessing the effectiveness of nucleoside reverse transcriptase antiretroviral therapy of an HIV-infected patient comprising evaluating whether a patient plasma sample contains nucleic acid encoding HIV reverse transcriptase (HIV-RT) having a mutation/insertion at codon 69, or at codons 69, 41, 215, or at codons 69, 62, 215, or at codons 69, 62, 74, or at codons 69, 41, 215, 210 (210, 75; 62; 62, 210); and method and resistance test vector for assessing the biological effectiveness of a candidate HIV antiretroviral drug compound comprising a patient-derived segment of reverse transcriptase which comprises a mutation at said codon(s).

2. claims: 8 - 16, 19 (partially)

Method for assessing the effectiveness of nucleoside reverse transcriptase antiretroviral therapy of an HIV-infected patient comprising evaluating whether a patient plasma sample contains nucleic acid encoding HIV-RT having a mutation at codon 62 or at codon 62 and further codons; and method and/or resistance test vector for assessing the biological effectiveness of a candidate HIV antiretroviral drug compound comprising a patient-derived segment of reverse transcriptase which comprises a mutation at said codon(s).

3. claims: Claims 8 - 16, 19 (partially)

Method for assessing the effectiveness of nucleoside reverse transcriptase antiretroviral therapy of an HIV-infected patient comprising evaluating whether a patient plasma sample contains nucleic acid encoding HIV-RT having a mutation at codon 75 or at codon 75 and further codons; and method and/or resistance test vector for assessing the biological effectiveness of a candidate HIV antiretroviral drug compound comprising a patient-derived segment of reverse transcriptase which comprises a mutation at said codons.

4. claims: Claims 8 - 16, 19 (partially)



The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

Method for assessing the effectiveness of nucleoside reverse transcriptase antiretroviral therapy of an HIV-infected patient comprising evaluating whether a patient plasma sample contains nucleic acid encoding HIV-RT having a mutation at codon 77 or at codon 77 and further codons; and method and/or resistance test vector for assessing the biological effectiveness of a candidate HIV antiretroviral drug compound comprising a patient-derived segment of reverse transcriptase which comprises a mutation at said codons.

5. claims: Claims 8 - 16, 19 (partially)

Method for assessing the effectiveness of nucleoside reverse transcriptase antiretroviral therapy of an HIV-infected patient comprising evaluating whether a patient plasma sample contains nucleic acid encoding HIV-RT having a mutation at codon 116 or at codon 116 and further codons; and method and/or resistance test vector for assessing the biological effectiveness of a candidate HIV antiretroviral drug compound comprising a patient-derived segment of reverse transcriptase which comprises a mutation at said codons.

6. claims: Claims 8 - 16, 19 (partially)

Method for assessing the effectiveness of nucleoside reverse transcriptase antiretroviral therapy of an HIV-infected patient comprising evaluating whether a patient plasma sample contains nucleic acid encoding HIV-RT having a mutation at codon 151 or at codon 151 and further codons; and method and/or resistance test vector for assessing the biological effectiveness of a candidate HIV antiretroviral drug compound comprising a patient-derived segment of reverse transcriptase which comprises a mutation at said codons.

The single general concept possibly linking inventions 1 to 6 appears to be the provision of methods and/or products for assessing drug effectiveness involving HIV-RT having a mutation at a certain codon. Methods and/or products for assessing drug effectiveness involving HIV-RT having a mutation at a certain codon are already disclosed in the prior art (cf. WO 97/27332 A: p. 4, 1, 15 - p. 5, 1, 6; Tables 1 - 3; cf. IVERSEN A K N et al. (1996): Table 1; cf. FITZGIBON J E et al (1995): tables 1, 2; cf. DE CLERCQ E (1997): Tables 2 - 5). Therefore, the Search Division is of the opinion that the above defined single general concept lacks novelty and thus does not represent a single general inventive concept. Hence, the present application lacks unity



European Patent  
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LACK OF UNITY OF INVENTION  
SHEET B

Application Number

EP 99 93 3581

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

(Art. 82 EPC).  
No further features shared by the 6 inventions listed above could be identified by the Search Division, which would be considered to be special technical features in the sense of Rule 30 EPC. Hence, the 6 inventions listed above are not unitary according to Article 82 EPC.

**ANNEX TO THE EUROPEAN SEARCH REPORT  
ON EUROPEAN PATENT APPLICATION NO.**

EP 99 93 3581

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.  
The members are as contained in the European Patent Office EPO file on  
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24-09-2004

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9727332	A 31-07-1997	AU 719691 B2 AU 1444397 A BR 9704637 A CA 2215073 A1 WO 9727332 A1 EP 0817866 A1 JP 11502727 T US 6331389 B1 US 6087093 A US 2003077575 A1	18-05-2000 20-08-1997 09-06-1998 31-07-1997 31-07-1997 14-01-1998 09-03-1999 18-12-2001 11-07-2000 24-04-2003
WO 9727319	A 31-07-1997	AU 732255 B2 AU 1952897 A CA 2216126 A1 CN 1213407 A DE 69711584 D1 DE 69711584 T2 EP 1170380 A2 EP 0852626 A1 ES 2175355 T3 HU 9900388 A2 JP 2000503849 T NO 983421 A NZ 331376 A PL 328068 A1 RO 118887 B1 WO 9727319 A1	12-04-2001 20-08-1997 31-07-1997 07-04-1999 08-05-2002 07-11-2002 09-01-2002 15-07-1998 16-11-2002 28-05-1999 04-04-2000 25-09-1998 27-03-2000 04-01-1999 30-12-2003 31-07-1997

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